K042313

DynamicImaging IntegradWeb

SEP - 9 2004

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared: August 1, 2004

Submitter's Information: 21 CFR 807.92(a)(1)

Dynamic Imaging, Inc.
110 Commerce Drive
Allendale, NJ 07401

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	INTEGRADWeb MPR/MIP ™ by Dynamic Imaging, Inc.
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050
Name:	System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	System, Image Processing	System, Image Processing
Regulation Number	892.2050	892.2050
510(k) Number	K031311	K040376
Device Name	INTEGRADWEB BY DYNAMIC IMAGING, INC	SECTRA IDS5 RADIOLOGY WORKSTATION; SECTRA MPR PAC
Applicant	Dynamic Imaging Inc.	Sectra-Imtec AB
Product Code	LLZ	LLZ
Decision Date	06/20/2003	05/04/2004

Device Description: 21 CFR 807 92(a)(4)

I INTEGRADWeb MPR/MIP ™ is an Internet based software picture archiving and communications system that provides users with capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. INTEGRAD*Web*™ includes features to access and manage medical imaging studies from cat-scan (CT), magnetic radiography (MR), ultrasound (US), nuclear medicine (NM), computerized radiography (CR), digital radiography (DR), digital x-ray (DX), x-ray angiography (XA), PET scan (PT), and other imaging modalities. INTEGRADWeb MPR/MIP ™ is designed to be deployed over conventional TCP/IP networking infrastructure available in most healthcare organizations, and utilizes commercially available computer platforms (Intel Pentium-based) and operating systems (Microsoft Windows 2000, Windows NT, and Windows 98).

The system does not produce any original medical images. All images located on INTEGRADWeb MPR/MIP ™ have been received from DICOM compliant modalities and/or systems.

Indications for Use: 21 CFR 807 92(a)(5)

INTEGRAD*Web* MPR/MIP™ by Dynamic Imaging, Inc. is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.
Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device is medical device image software that is used with computer hardware in a picture archiving and communications system user environment. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification INTEGRADWeb MPR/MIP ™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. The system has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2004

Dynamic Imaging, Inc.
% Mr. Ned Devine
Responsible Third Party Official
Entela, Inc.
3033 Madison Ave., SE
GRAND RAPIDS MI 49548

Re: K042313
Trade/Device Name: INTEGRAD*Web* MPR/MIP™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 24, 2004
Received: August 26, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: **K042313**

Device Name: INTEGRAD*Web* MPR/MIP™

Indications for Use:

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Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.

Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R Seyran

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042313